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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PILLSBURY WINTHROP, LLP
P.O. BOX 10500
MCLEAN, VA 22102

EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM -

Office Action Summary	Application No.	Applicant(s)	
	09/986,174	HANNA, NABIL	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2001*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims **1-6**, and **15** link(s) inventions groups 1)-8). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-6. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. Invention groups 9-16, drawn to method of enhancing apoptosis using the 8 different immunoconjugates, and invention groups 17-24, drawn to nucleic acid molecules encoding the 8 different immunoconjugates, and methods of treating with the 8 different immunoconjugates in combination with other chemotherapeutic agents are also different inventions.

1). Claim 7, drawn to an immunoconjuate comprising antibody capable of binding to CD20, classified in class 530, subclass 387.1.

2). Claim 8, drawn to an immunoconjuate comprising antibody capable of binding to CD19, classified in class 530, subclass 387.1.

3). Claim 9 drawn to an immunoconjuate comprising antibody capable of binding to CD22, classified in class 530, subclass 387.1.

4). Claim 10, drawn to an immunoconjuate comprising antibody capable of binding to CD33, classified in class 530, subclass 387.1.

5). Claim 11, drawn to an immunoconjuate comprising antibody capable of binding to CD38, classified in class 530, subclass 387.1.

6). Claim 12, drawn to an immunoconjuate comprising antibody capable of binding to HER-2, classified in class 530, subclass 387.1.

7). Claim 13, drawn to an immunoconjuate comprising antibody capable of binding to TAG-72, classified in class 530, subclass 387.1.

8). Claim 14, drawn to an immunoconjuate comprising antibody capable of binding to MUC-1, classified in class 530, subclass 387.1.

9). Claim 16, and 17 partially, drawn to a method of enhancing apoptosis by administering an immunoconjuate comprising antibody capable of binding to CD20, classified in class 424, subclass 178.1.

10). Claim 16, and 17 partially, drawn to a method of enhancing apoptosis by administering an immunoconjuate comprising antibody capable of binding to CD19, classified in class 424, subclass 178.1.

11). Claim 16, and 17 partially drawn to a method of enhancing apoptosis by administering an immunoconjuate comprising antibody capable of binding to CD22, classified in class 424, subclass 178.1.

12). Claim 16, and 17 partially, drawn to a method of enhancing apoptosis by administering an immunoconjuate comprising antibody capable of binding to CD33, classified in class 424, subclass 178.1.

13). Claim 16, and 17 partially, drawn to a method of enhancing apoptosis by administering an immunoconjuate comprising antibody capable of binding to CD38, classified in class 424, subclass 178.1.

14). Claim 16, and 17 partially, drawn to a method of enhancing apoptosis by administering an immunoconjuate comprising antibody capable of binding to HER-2, classified in class 424, subclass 178.1.

15). Claim 16, and 17 partially, drawn to a method of enhancing apoptosis by administering an immunoconjuate comprising antibody capable of binding to TAG-72, classified in class 424, subclass 178.1.

16). Claim 16, and 17 partially, drawn to a method of enhancing apoptosis by administering an immunoconjuate comprising antibody capable of binding to MUC-1, classified in class 424, subclass 178.1.

17). Claim 18, and 19 partially, drawn to a nucleic acid encoding an immunoconjuate comprising antibody capable of binding to CD20, classified in class 536, subclass 23.1.

18). Claim 18, and 19 partially, drawn to a nucleic acid encoding an immunoconjuate comprising antibody capable of binding to CD19, classified in class 536, subclass 23.1.

19). Claim 18, and 19 partially, drawn to a nucleic acid encoding an immunoconjuate comprising antibody capable of binding to CD22, classified in class 536, subclass 23.1.

20). Claim 18, and 19 partially, drawn to a nucleic acid encoding an immunoconjuate comprising antibody capable of binding to CD33, classified in class 536, subclass 23.1.

21). Claim 18, and 19 partially, drawn to a nucleic acid encoding an immunoconjuate comprising antibody capable of binding to CD38, classified in class 536, subclass 23.1.

22). Claim 18, and 19 partially, drawn to a nucleic acid encoding an immunoconjuate comprising antibody capable of binding to HER-2, classified in class 536, subclass 23.1.

23). Claim 18, and 19 partially, drawn to a nucleic acid encoding an immunoconjuate comprising antibody capable of binding to TAG-72, classified in class 536, subclass 23.1.

24). Claim 18, and 19 partially, drawn to a nucleic acid encoding an immunoconjuate comprising antibody capable of binding to MUC-1, classified in class 536, subclass 23.1.

25). Claim 20-22 partially, drawn to method of combination therapy using an immunoconjuate comprising antibody capable of binding to CD20, classified in class 424, subclass 178.1.

26). Claim 20-22 partially, drawn to method of combination therapy an immunoconjuate comprising antibody capable of binding to CD19, classified in class 424, subclass 178.1..

27). Claim 20-22 partially, drawn to method of combination therapy an immunoconjuate comprising antibody capable of binding to CD22, classified in class 424, subclass 178.1.

28). Claim 20-22 partially, drawn to method of combination therapy an immunoconjuate comprising antibody capable of binding to CD33, classified in class 424, subclass 178.1.

29). Claim 20-22 partially, drawn to method of combination therapy an immunoconjuate comprising antibody capable of binding to CD38, classified in class 424, subclass 178.1.

30). Claim 20-22 partially, drawn to an immunoconjuate comprising antibody capable of binding to HER-2, classified in class 424, subclass 178.1.

31). Claim 20-22 partially, drawn to an immunoconjuate comprising antibody capable of binding to TAG-72, classified in class 424, subclass 178.1.

32). Claim 20-22 partially, drawn to an immunoconjuate comprising antibody capable of binding to MUC-1, classified in class 424, subclass 178.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1)-8) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different products capable of binding to different antigens.

Inventions 16)-24) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different nucleic acids molecules encoding products capable of binding to different antigens.

Inventions of the product groups 1)-8), and the inventions of the method groups 9)-15) or the inventions of the method groups 25)-32) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, each of the products in the invention groups 1)-8) as claimed can be used in a materially different process of enhancing apoptosis as in groups 9)-15), or alternatively in the process of combination therapy method as in groups 25)-32).

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification. The search required for each of the above inventions is not coextensive with regard to the literature and the

sequence searches. Further, a reference which would anticipate the invention of any one group would not necessarily anticipate or make obvious the any of the other groups. For these reasons, restriction for examination purposes is proper.

Groups 1)-32) above contain the following two genuses of patentably distinct species: the species of the first genus are IFN-alpha-2a, IFN-alpha-2b, and IFN-alpha-2n1 as claimed in claim 4. The species of the second genus are a breast carcinoma cell, an ovarian carcinoma cell, a prostate carcinoma cell, a lung carcinoma cell, a leukemic T cell, a leukemic B cell, a multiple myeloma cell, and a B cell lymphoma cell as claimed in claim 5.

If any of Groups 1)-32) is elected, applicant is required under 35 U.S.C. 121 to elect each of a single disclosed species from the two genuses, even though this requirement is traversed.

Further, Groups 25)-32) above contain claims generic to a plurality of disclosed patentably distinct species (claimed in claims 21 and 22). They are ara-c, doxorubicin, idarubicin, mitoxantrone, chlorambucil, melphalan, 6- mercaptopurine, 6-thioguanine, dibromomannitol, IFN-C, 2- chlorodeoxyadenosine, deoxycoformycin, dacarbazine, cisplatin, carmustine, lomustine, tauromustine, fotemustine, carboplatin, vincristine, vinblastine, vindesine, taxol, dibromodulcitol, detorubicin, piritrexin, estramustine, paclitaxel, navelbine, prenisolone, ABDIC, ABVD, Ara-c, AVD, CAF, CAMP, CAP, CAP-BOP, CAVP, CEVD, CDDP+VP- 16, CEF, CEM, CEP, CEPPIB), CEVD, ChIVPP, CHOP, CHOP-B, CMF, CMP, CMVP, CVP, DHAP, ESHAP, EPOCH, EVA, EVAP, IFN-C, IMVP-I6, MACOP-B, m-BACOD, MIME, MINE, MOPLACE, MOPP, MOPP+ABV,

MOPP+ABVD, MVPP, MTX-CHOP, PCVP, PrOMACE- CWaBOM, PrOMACE-MOPP, VABCD, VAT or VATH.

If any of group 25)-32) above is elected, applicant is required under 35 U.S.C. 121 to elect each of a single disclosed species from the three genuses, even though this requirement is traversed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642